REMARKS

I. Status of the Claims and Support for the Amendments

Claims 28 and 55 are currently amended.

Claims 28–30, 48–52, and 55–62 are currently pending.

Support for the amendment of the claims is implicit in the claims as originally filed.

II. Rejection under 35 U.S.C. § 112

Claims 28–30, 48–52, and 55–62 are rejected under 35 U.S.C. § 112, second paragraph as allegedly being indefinite.

A. The rejection alleges, in part, that claims 28 and 55 are confusing for their use of the term "Formula II". The examiner suggests that each time "Formula II is recited for R_2 it should refer to the definition as recited above instead of reciting it or not reciting it... ." Applicant responds as follows.

Applicant does not concede that the use of the term "Formula II", in the examined claims, was confusing. Nevertheless, in order to facilitate advancement to grant, Applicant has amended the claims as per the Examiner's suggestion. That is, in claims 28 and 55 at the second and each subsequent use of the term "Formula II" to define the constituents of R_2, the claims are amended to insert the phrase "as defined above" to more clearly indicate the meaning of the phrase "Formula II".

B. The rejection further recites that "the phrase 'administering to a patient' should be amended to recite 'the' or 'said' patient to make it clear that the patient is the same one in need of the recited method." In response, Applicant has amended the claims to recite "to the patient", as suggested.

Applicant believes that these amendments overcome the rejections under 35 U.S.C. § 112. Accordingly, the rejection may now properly be withdrawn.

III. Rejection under 35 U.S.C. § 103

Claims 28–30, 48–52, and 55–62 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Burzynski *et al.* as disclosed in the specification at page 5 (*Drugs Exptl. Clin. Res.* 12 Suppl. 1, 25–35 (1986)) in view of Waldbillig (Report filed with FDA, dated March 14, 1997). Specifically, the rejection recites:

> Burzynski teaches using the instant compounds to treat cancer. Burzynski does not teach the instant concentration. However, Waldbillig (page 3, 9–11, among others) discloses pulsing the instant compounds using the instant concentrations.
>
> The claims differ over the references in reciting a ratio of the compounds, specific dosages, rates of infusion and combined concentration of compounds. However, in the absence of a showing of unexpected results no unobviousness is seen in said limitations, since once the usefulness of a composition is taught it is within the skill of the artisan to determine said limitations.

Applicant respectfully traverses.

Applicant believes that the rejection is improper and should be withdrawn, as the Waldbillig report is not prior art under 35 U.S.C. §§ 102 or 103. As set out in the accompanying 37 C.F.R. § 1.132 Declaration by Stanislaw R. Burzynski, M.D., Ph.D., the Waldbillig report was submitted to the United States Food and Drug Administration (hereinafter, "FDA") as part of an annual report for investigational new drug (IND) #43,742. Such reports are held in confidence by the FDA and are not published or otherwise made publicly available. Accordingly, the Waldbillig report is cannot properly be considered prior art under 35 U.S.C. §§102–103. The report was included as part of Applicant's previous submission in order to facilitate the Examiner's assessment of the patentability of the instant invention by providing further evidence of the efficacy of Applicant's invention. It was not submitted as, and is not considered by Applicant to be, a prior art reference.

Given that the Waldbillig report is not prior art, there is nothing in Burzynski *et al.*, taken either alone or in combination with the prior art, that would teach or suggest the instantly

claimed invention to one of ordinary skill in the art (for more details, see Applicant's response dated September 8, 2004, pages 12–14). As the Examiner points out, Burzynski *et al.* does not teach or suggest the advantage of using the instantly claimed concentrations. Likewise, Burzynski *et al.* does not teach or suggest the advantage of the currently claimed infusion rates. Accordingly, Applicant believes that the current rejection under 35 U.S.C. § 103(a) has been overcome and may now properly be withdrawn.

IV. Double Patenting

Claims 28–30, 48–52, and 55–62 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 7–11 of U.S. Patent No. 6,258,849. The rejection specifically alleges that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because '849 discloses the method of using the compounds of Formulas I and II[I] and its 'comprising' language...would allow for the addition of the compound of formula IV." Applicant respectfully traverses.

As recited in MPEP §804.01:

> The third sentence of 35 U.S.C. § 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent...This apparent nullification of double patenting as a ground of rejection or invalidity in such case imposes a heavy burden on the Office to guard against erroneous requirements for restrictions... ."

Thus, if a claimed invention was subject to restriction in an application, rejection of such invention for double patenting is prohibited in any divisional application claiming the benefit of continuity with the application for which the restriction requirement was issued.

Applicant believes that current the double patenting rejection is improper, because the present circumstances meet the elements set out in 35 U.S.C. § 121 and MPEP §804.01. First, a restriction requirement was made in U.S. patent application serial number, 09/121,567 (which

issued as U.S. Pat. No. 6,258,849) that covers the currently pending claims. Second, the present divisional application was filed before the issuance of the '849 patent (and claims priority to the '567 application).

Claims 7–11 of the '849 patent are drawn to methods of treating neoplastic disease using a combination of compounds of Formula I and compounds of Formula III. This "invention" is covered by *group I* of the restriction requirement dated August 6, 1999, issued in the '567 application (for the Examiner's convenience, a copy of this restriction requirement is enclosed). The restriction requirement defines *group I* claims as "drawn to compositions and methods for treating cancer with an enhanced combination of Formulas I and III." The *group I* claims were prosecuted in the '567 application.

Other groups defined in the August 6, 1999 restriction requirement are explicitly drawn to methods of using the compounds of Formulas I and III in combination with compounds of Formula IV. For example, *group VI* is "drawn to a method for treating cancer employing a combination of Formulas I and III and a combination of Formulas IV and I." Similarly, *group VII* is "drawn to a method for treating cancer employing a combination of Formulas I and III and a combination of Formulas IV and III.

Therefore, in view of the August 6, 1999 restriction requirement, issued during the prosecution of the '849 patent, the currently pending claims fall squarely under the provisions of 35 U.S.C. § 121 and MPEP §804 and are not properly subject to a double patenting rejection over the '849 patent. Accordingly, Applicant believes that this rejection has been overcome and may now properly be withdrawn.

V. Conclusion

In view of the foregoing Amendments and Remarks, Applicant believes that all remaining rejections of the claims have been overcome and that the case is in condition for advance to allowance. Accordingly, Applicant respectfully requests favorable reconsideration of the case and issuance of a Notice of Allowance therefor.

The Examiner is invited to contact the undersigned attorney at 713.787.1589 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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